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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
SPARTANBURG DIVISION

State of South Carolina)
Ex rel. Henry McMaster, in his)
capacity as Attorney General of the)
State of South Carolina,) C.A. No. 7:07-1875-HMH
)
Plaintiff,)
) **OPINION & ORDER**
vs.)
)
Eli Lilly & Company, Inc.,)
)
Defendant.)

This matter is before the court on the State of South Carolina's (the "State") motion to remand. For the reasons set forth below, the court grants the State's motion.

I. FACTUAL AND PROCEDURAL BACKGROUND

On May 25, 2007, the State filed the instant action against Eli Lilly & Company, Inc. ("Lilly") in the Court of Common Pleas for the Seventh Judicial Circuit, Spartanburg County, South Carolina. The complaint states the following claims, all of which arise pursuant to state law: submission of false and fraudulent claims under the Medicaid program pursuant to S.C. Code Ann. §§ 43-1-60 and 43-7-60; recovery of treatment costs caused by Lilly's product as parens patriae, or alternatively, under S.C. Code Ann. § 43-7-420; violation of the South Carolina Unfair Trade Practices Act; negligence; breach of warranty; fraud and misrepresentation; and unjust enrichment.

On July 6, 2007, Lilly removed this action to federal court pursuant to 28 U.S.C. §§ 1331, 1441, and 1446, alleging that the complaint raises substantial issues of federal law. The State filed the instant motion on July 13, 2007.

II. DISCUSSION OF LAW

Lilly was entitled to remove the instant case if the State could have brought it in federal district court originally pursuant to 28 U.S.C. § 1441(a) as a civil action “arising under the Constitution, laws, or treaties of the United States.” 28 U.S.C. § 1331. Lilly asserts that federal jurisdiction exists because the complaint, which asserts state-law claims, raises substantial and disputed issues of federal law. (Def.’s Mem. Opp’n Mot. Remand 3, 6.) Specifically, Lilly contends that jurisdiction exists because the State’s complaint raises federal questions regarding (1) the meaning and application of the federal term “medically accepted indication” as that term is defined by 42 U.S.C. 1396r-8(k)(6); (2) “[w]hether Lilly violated the FDCA by allegedly marketing Zyprexa medicines for non-approved uses;” and (3) “[w]hether the FDA would have allowed Lilly to re-write Zyprexa’s FDA-approved label to reflect what the State alleges the label should have stated regarding the risk of diabetes.” (Id. 3.)

“[I]n certain cases federal-question jurisdiction will lie over state-law claims that implicate significant federal issues.” Grable & Sons Metal Prods. v. Darue Eng’g & Mfg., 545 U.S. 308, 312 (2005) “[T]he question is, does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.” Id. at 314. Further, “[i]t is elementary that the burden is on the party asserting jurisdiction to

demonstrate that jurisdiction does, in fact, exist." Lovern v. Edwards, 190 F.3d 648, 654, (4th Cir. 1999).

For federal-question jurisdiction to arise, there must exist "not only a contested federal issue, but a substantial one, indicating a serious federal interest in claiming the advantages thought to be inherent in a federal forum." Grable, 545 U.S. at 313. The complaint alleges various tortious acts committed by Lilly, including inducing the submission of false and fraudulent claims under the State's Medicaid program and falsely representing that Zyprexa is safer and more effective than less expensive antipsychotics. (Compl. ¶¶ 96-109.) Further, the State alleges that Lilly promoted Zyprexa for non-medically accepted indications and non-medically necessary uses, and "actively concealed" such promotion from the State. (Id. ¶ 98-99.) In addition, the State alleges that Lilly failed to disclose or warn of the side effects of Zyprexa, and that Lilly engaged in an illegal scheme of "off-label promotion" of Zyprexa. (Id. ¶¶ 39, 44, 50, 61, 98, 114, 136.)

The Federal Medicaid Act allows states to "exclude or otherwise restrict coverage of a covered outpatient drug if . . . the prescribed use is not for a medically accepted indication . . ." 42 U.S.C. § 1396r-8(d)(1)(B) (West Supp. 2007). In addition, the Act defines the term "medically accepted indication." 42 U.S.C. § 1396r-8(k)(6) (West Supp. 2007). Thus, Lilly argues that a federal issue presented by the complaint is whether prescriptions that the State alleges should not have been reimbursed were in fact authorized by – and required to be covered under – federal Medicaid law. (Def.'s Mem. Opp'n Mot. Remand 12-13.)

The court finds that in the instant case, no substantial federal question exists to support a finding of jurisdiction. Lilly's liability will solely depend upon its breach of duties as

defined and created by state law. "Simply put, it is not the act of causing the submission of a claim for a non-medically accepted indication that creates liability under the state law causes of action, but rather the act of causing the submission of a false or fraudulent claim."

Pennsylvania v. Eli Lilly & Co., Inc., No. 07-1083, 2007 WL 1876531, at *5 (E.D. Pa. June 27, 2007). For example, if the State proves at trial that Lilly violated the Federal Medicaid Act, it would not necessarily follow that Lilly committed Medicaid fraud as defined in S.C. Code Ann. §§ 43-7-60.

Thus, while the prescription of the drugs for such "off-label" uses was the alleged goal – and the alleged harm – the submission of claims for non-medically accepted indications or non-medically necessary uses was not in and of itself the tortious conduct. In other words, the central dispute in this case . . . will be factual. Here the central question is whether the Defendants' advertising and promotion methods violate [South Carolina] tort law, not what is or is not a medically accepted indication or medically necessary use. The alleged acts and omissions by the Defendants allegedly constitute a failure to warn, negligence, breach of warranty, fraud and misrepresentation under [South Carolina] law not merely because the Defendants promoted their drug for off-label uses, but because they allegedly intentionally misrepresented their drug's efficacy and risks for such uses.

Eli Lilly & Co., Inc., 2007 WL 1876531, at *4; see also Alaska v. Eli Lilly & Co., No. 3:06-CV-88 TMB, 2006 WL 2168831, at *1-3 (D. Al. July 28, 2006) (finding no federal jurisdiction over state law claims alleging that "[the defendant] advertised and sold Zyprexa for a number of non-approved 'off-label' uses"). These circumstances are clearly distinguishable from Grable, which found federal question jurisdiction where the meaning of a federal statute was "the only legal or factual issue contested . . ." Grable, 545 U.S. at 315. The incidental federal issues that may arise in this case do not rise to the level of substantiality required for a finding of federal jurisdiction.

Furthermore, even if Lilly could demonstrate the existence of a substantial and contested federal question in the instant case, “the federal issue will ultimately qualify for a federal forum only if federal jurisdiction is consistent with congressional judgment about the sound division of labor between state and federal courts governing the application of § 1331.” Grable, 545 U.S. at 313-14. Lilly has failed to make this showing.

In general, “the absence of a federal private right of action [is] evidence relevant to, but not dispositive of, the sensitive judgments about congressional intent that § 1331 requires.” Id. at 318 (internal quotation marks omitted). However, in contrast to the facts in Grable, a finding of federal jurisdiction over any state cause of action implicating provisions of the Federal Medicaid Act and its accompanying regulations could “attract[] a horde of original filings and removal cases raising other state claims with embedded federal issues.” Id. Under these circumstances, the fact that Congress provided no private right of action in the Federal Medicaid Act presents compelling evidence that a finding of federal jurisdiction in the instant case would not be “consistent with congressional judgment about the sound division of labor between state and federal courts.” Id. at 313.

Further supporting this finding is the fact that the Federal Medicaid Act requires states to seek recovery of Medicaid funds from liable third parties. 42 U.S.C. § 1396a(a)(25) (West Supp. 2007); see New York v. Lutheran Center for the Aging, Inc., 957 F. Supp. 393, 403 (E.D.N.Y. 1997) (“Where a federal statute such as Medicaid requires a state to enforce liability against a third party but does not provide the ground for that liability, nor require establishment of a ground for liability, federal question jurisdiction will not lie.”) Therefore, a finding of federal jurisdiction in the instant case would not be “consistent with congressional

judgment about the sound division of labor between state and federal courts." Grable, 545 U.S. at 313. Based on the foregoing, the State's motion to remand is granted.

Therefore, it is

ORDERED that the Plaintiff's motion to remand, docket number 9, is granted.

IT IS SO ORDERED.

s/Henry M. Herlong, Jr.
United States District Judge

Greenville, South Carolina
August 3, 2007